REMARKS

Claims 27-40 were pending in the present application. Claims 36 and 39-40 have been canceled, without prejudice. Accordingly, claims 27-35 and 37-38 will be pending upon entry of the instant amendment. Any cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to expedite prosecution of the application. No new matter has been added by way of amendment and Applicants submit that all of the claims are now in condition for allowance.

Objections

The Examiner has objected to the specification because the Related Applications section on page 1 of the specification did not properly reflect the status of the parent application. Applicants have amended the specification in order to properly reflect the status of the parent application.

The declaration was objected to by the Examiner as being defective due to non-initialed and non-dated alterations of the residence by the inventor. Applicants submit herewith a substitute executed declaration in which the inventor's information has been properly corrected.

The specification was objected to because the title "is not descriptive". Applicants have amended the title to read "CARDIOVASCULAR SYSTEM ASSOCIATED PROTEIN KINASE 2 (CSAPK-2) ANTIBODIES" in order for the title to be descriptive of the invention to which the claims are directed.

Claims 38 and 39 were rejected to due to informalities. Applicants have amended claims 38 and 39 as suggested by the Examiner, thereby obviating the objection.

Applicants have addressed all of the objections raised by the Examiner and therefore respectfully request reconsideration and withdrawal of the foregoing objections.

The Rejection of Claim 36 under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claim 36 was rejected under 35 U.S.C. § 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed." Specifically, claim 36 was rejected because the claim introduces the term "human antibody", which is considered by the Examiner as "New Matter". In the interest of expediting prosecution, and without acquiescing to the Examiner's rejection, Applicants have canceled claim 36, thereby obviating the 35 U.S.C. §112, first paragraph rejection of claim 36. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing rejection.

The Rejection of Claims 27-40 under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claims 27-40 were rejected under 35 U.S.C. § 112, first paragraph, because the specification does not provide "sufficient guidance and direction as to make and use antibodies, wherein the antibodies bind any polypeptide fragment of SEQ ID NO:5, encoded by any fragment of SEQ ID NO:4 or 6; or any fragment of the plasmid deposited with the ATCC as Accession number 203306." Specifically, the Examiner states that:

> "[t]he specification, while being enabling for an antibody or portion thereof that specifically binds to SEQ ID NO:5, and amino acid 31-277 and 407-421 fragments for diagnostic tests, does not reasonably provide enablement for an isolated antibody, or portion thereof, that specifically binds to (a) any polypeptide "comprising" the amino acid sequence set forth in SEQ ID NO:5 or any "fragment thereof" in claim 27, (b) any polypeptide encoded by the nucleic acid molecule "comprising" the nucleotide sequence of SEQ ID NO:4 or 6, or any "fragment thereof" in claim 28, (c) any polypeptide encoded by a nucleic acid molecule comprising the nucleotide sequence contained in the plasmid deposited with the ATCC as Accession Number 203306 or any "fragment thereof" in claim 29, wherein the said antibody binds to any "fragment" of said polypeptide "comprising" amino acid residues 31-277 of SEQ ID NO:5 in claim 38, wherein said antibody binds to any "fragment" of said polypeptide "comprising" amino acid residues 407-421 of SEQ ID No:5 in claim 39."

The Examiner also states that "the specification fails to provide sufficient disclosure of amino acid fragments that maintain the structural and functional properties of the CSAPK-2 activity set forth in SEQ ID NO:5, wherein the fragment is immunogenic." Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, Applicants have amended claims 27, 28, 29, 38 and 39 to read an antibody, or portion thereof, that specifically binds to the amino acid sequence specified in each claim or to the polypeptide encoded by the nucleic acid sequence specified in each claim. Applicants have additionally amended these claims to read that the "fragments thereof" have protein kinase activity.

The limitations within newly amended claims 27, 28, 29 and 38 are fully enabled within the specification as Applicants have provided teachings for every element needed for one of skill in the art to practice the claimed invention. Firstly, Applicants have taught a domain within the CSAPK-2 polypeptide which is conserved and essential for activity of the polypeptide, namely the dual specificity kinase catalytic domain (refer to page 14, beginning on line 19). By having identified a region necessary for activity, Applicants have taught which regions of the polypeptide are amenable to alterations as well as those which are not amenable to alterations. Secondly, the specification teaches one how to generate functional variants by performing conservative substitutions within the polypeptide used in the claimed invention. As defined on page 26, "[c]onservative amino acid substitutions are made at one or more predicted non-essential amino acid residues. A "conservative amino acid substitution" is one in which the amino acid residue is replaced with an amino acid residue having a similar side chain." The Applicants have also defined which of the amino acids have similar side chains, thereby providing a skilled artisan the necessary tools to generate functional variants of the polypeptide used in the claimed invention. Thirdly, not only have the Applicants provided the teachings for generating such functional variants, Applicants have provided an example of a specific fragment of SEQ ID NO:5 which exhibits protein kinase activity, namely the dual specificity kinase catalytic domain located at about residues 31-277 of SEQ ID NO:5 (refer to page 14, beginning at line 19).

Finally, Applicants have provided teachings for one of skill in the art to be able to perform assays to determine whether or not specific sequences have the desired protein kinase activity. As taught on pages 26 and 27 of the specification, beginning on line 36 of page 26,

mutated CSAPK polypeptides can be expressed recombinantly and the activity of the protein can be determined by performing assays which measure the protein's ability to: 1) regulate transmission of signals from cellular receptors, e.g., cardiac cell growth factor receptors; 2) control entry of cells, e.g., cardiac cells, into mitosis; 3) modulate cellular differentiation; 4) modulate cell death; or 5) regulate cytoskeleton function, e.g., actin bundling. Performing such assays to determine whether or not a fragment or mutant of SEQ ID NO:5 has the desired properties and then generate antibodies to those fragments identified as having the desired activity would not constitute undue experimentation. Therefore, Applicants have provided all of the necessary information to enable one of skill in the art to 1) identify regions within the polypeptide used in the claimed invention which may be altered while maintaining activity; 2) generate fragments; 3) perform assays to determine whether or not the sequences generated do in fact have the desired protein kinase activity; and 4) generate antibodies to fragments identified.

Therefore, contrary to the Examiner's assertions, Applicants have provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of claims 27-35 and 37-38. Therefore, Applicants respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 27-40.

The Rejection of Claims 27-40 under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claims 27-40 are rejected under 35 U.S.C. § 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

Specifically, the Examiner states that:

> "Applicant is not in possession of an isolated antibody, or a portion thereof, that specifically binds to (a) any polypeptide "comprising" the amino acid sequence set forth in SEQ ID NO:5 or any "fragment thereof" in claim 27, (b) any polypeptide encoded by the nucleic acid molecule "comprising" the nucleotide sequence of SEQ ID NO:4 or 6, or any "fragment thereof" in claim 28, (c) any polypeptide encoded by a nucleic acid molecule "comprising" the nucleotide sequence contained in the plasmid deposited with

the ATCC as Accession Number 203306 or any "fragment thereof" in claim 29, wherein the said antibody binds to any "fragment" of said polypeptide "comprising" amino acid residues 31-277 of SEQ ID NO:5 in claim 38, wherein said antibody binds to any "fragment" of said polypeptide "comprising" amino acid residues 407-421 of SEQ ID NO:5 in claim 39."

Applicants respectfully traverse this rejection, however in the interest of expediting prosecution, and in no way acquiescing to the Examiner's rejection, Applicants have amended claims 27, 28, 29 and 38 to read an isolated antibody, or portion thereof, that specifically binds to the amino acid sequence specified in each claim or to the nucleic acid sequence specified in each claim. Applicants have additionally amended these claims to read that the "fragments thereof" have protein kinase activity. In light of these newly amended claims, Applicants traverse the Examiner's rejection and argue that they were in possession of the claimed invention at the time of filing for the reasons discussed below.

The Examiner is of the opinion that the specification filed by Applicants had not disclosed the claimed genus of antibodies which are capable of specifically binding to polypeptide fragments of SEQ ID NO:5 and hence Applicants were not entitled to such genus claims. As discussed in depth above, the specification provides a sufficiently descriptive disclosure on how to: 1) generate antibodies capable of specifically binding to the CSAPK-2 sequence (SEQ ID NO:5); 2) generate functionally active fragments of the CSAPK-2 sequence (SEQ ID NO:5); 3) determine whether or not fragments generated have the desired protein kinase activity using various assays; and 4) generate antibodies capable of binding to other functionally active fragments of CSAPK-2 having the desired protein kinase activity. Therefore, contrary to the Examiner's assertions, Applicants have provided the necessary teachings to demonstrate that they were in possession of the claimed invention at the time of filing, by having not only provided antibodies capable of specifically binding to the full length sequence of the CSAPK-2 polypeptide, but also by having provided antibodies capable of specifically binding to a functional fragment of the CSAPK-2 polypeptide having the desired activity and an enabling disclosure for obtaining other such antibodies capable of specifically binding to functional CSAPK-2 sequences. Applicants, therefore, respectfully request reconsideration and withdrawal of the foregoing 35 U.S.C. § 112, first paragraph rejection over claims 27-40.

CONCLUSIONS

In view of the amendments and remarks made herein, Applicants respectfully submit that the objections and rejections presented by the Examiner are now overcome and that this application is now in condition for allowance. Early notice to this effect is solicited.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

It is believed that this paper is being filed timely and that a one month extension of time is required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

Respectfully submitted,

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